

Remarks

Applicant respectfully requests reconsideration of the claim for domestic priority under 37 CFR §119(e) in view of the claims as currently amended. It is respectfully submitted that the provisional application does indeed provide support for claims in their current form as is discussed below. Accordingly, it is believed that the request for the claims for domestic priority should be granted.

Claim 175 has been cancelled and claim 177 has been added. Thus, claims 172-174, 176 and 177 are currently pending in the instant application.

New claim 177 is based on claims 173 and 175. Claim 177 is similar to claim 173 and also recites that the corn grain has an oil content in the range from about 6% to about 10% on a dry matter basis and further wherein said oil is comprised of not less than 60% oleic acid of the total oil content of the seed. Thus, no new matter has been added.

Claims 172-176 were rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Reference to the "or a subsequence of SEQ ID NO:9 having at least 500 nucleotides: has been deleted. The claims now recite that "all or part of the isolated nucleic acid fragment is useful in co-suppressing an endogenous gene encoding a corn delta-9 stearoyl ACP desaturase. . . "

Support for this can be found in the specification on page 17 at lines 4-14, page 21 at lines 23-25, Example 1 and elsewhere in the specification. Thus, no new matter has been added.

Withdrawal of this ground of rejection is respectfully requested in view of the amendment of the claims.

Claims 172-176 were rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

First, Applicants respectfully submit that there is a clear correlation between structure and function. All of the claims clearly recite that the isolated nucleic acid fragment encodes either a corn delta-9 stearoyl ACP desaturase or a corn delta-12 desaturase. Clearly, the claims recite that the isolated nucleic acid fragment encodes desaturase. Those skilled in the relevant art understand that a desaturase is an enzyme having that particular activity.

Attention is kindly invited to WO 91/13972, published September 19, 1991, which describes desaturase enzymes relevant to fatty acid synthesis in plants, especially delta-9 desaturases and U.S. Patent No. 5, 443,974, issued to Hitz et al.

on August 22, 1995, describes the preparation and use of nucleic acid fragments encoding soybean seed stearyl-ACP desaturase enzymes or its precursor to modify plant oil composition.

Attention is also kindly invited to WO 94/11516, published May 26, 1994, which describes genes for microsomal delta-12 desaturases and related enzymes from plants. The cloning of a corn (*Zea mays*) cDNA encoding seed microsomal delta-12 fatty acid desaturase is described. The discussion of that citation was incorporated by reference.

These references further support and demonstrate the correlation between function and activity of the claimed sequences.

With respect to SEQ ID NO:9, the claims now recite that the isolated nucleic acid fragment encodes a corn delta-9 stearyl ACP desaturase consisting essentially of the amino acid sequence set forth in SEQ ID NO:9. Furthermore, the claims also recite that all or part of the isolated nucleic acid fragment is useful in co-suppressing an endogenous gene encoding a corn delta-9 stearyl ACP desaturase.

Support for this can be found in the specification on page 17 at lines 4-14 which discusses co-suppression and also references Jorgenson's work in this area by citing U.S. Patent No. 5, 231,020. It is stated on page 21 of the specification at lines 23-25 that "**All or a portion** of the coding sequence of the trait gene is located 3 to the Sh1 exon/intron1 sequence and may be in a **sense** or antisense orientation." (Emphasis added.) Thus, no new matter has been added.

With respect to SEQ ID NO:1 and delta-12 desaturase, the claims also recite that all or part of the isolated nucleic acid fragment is useful in co-suppressing an endogenous gene encoding a corn delta-12 desaturase. It is noted that the disclosure of WO 94/11516, published May 26, 1994, is incorporated by reference. (Specification page 6 at lines 1-4.) It is stated in Example 1 of the specification on page 30 at lines 26-32 that:

A corn embryo cDNA library was screened using a radioisotopically-labeled DNA fragment obtained by PCR and containing the corn gene for delta-12 desaturase ("**fad2-1**", **WO 94/11516**, and **set forth in SEQ ID NO:1**). A second delta-12 desaturase cDNA clone was identified on the basis of its sequence. The second gene for delta-12 desaturase is designated fad2-2. (Emphasis added).

WO 94/11516 provides additional information regarding the correlation between the structure and function of nucleic acid fragments encoding a delta-12 desaturase from a variety of crops such as corn, soybean, *Brassica*, etc. The disclosure of which was incorporated by reference.

It is also stated in Example 1 on page 31 at lines 1-4 that a “**full-length ratio of the coding region of either one of genes in either antisense or sense approach may be used to suppress both the fad2-1 and fad2-2 genes or gene products**, due to the significant homology in the coding region between the fad2-1 and fad2-2 genes, and thus produce a high oleate phenotype in transgenic corn.”

WO 94/11516 also provides additional information how to identify such nucleic acid fragments.

In view of the foregoing information and discussion, Applicants respectfully request withdrawal of the rejection of the claims under 35 USC §112, first paragraph.

Claims 172 and 176 were rejected under 35 USC §103(a) as being unpatentable over Hitz et al. (US 5443974) in view of Zwick et al. (US 6350934).

U.S. Patent No. 5, 443,974, issued to Hitz et al. on August 22, 1995, describes the preparation and use of nucleic acid fragments encoding soybean seed stearoyl-ACP desaturase enzymes or its precursor to modify plant oil composition.

Hitz et al. states in column 2 at lines 12-21 that “A soybean oil **low in total saturates and polyunsaturates and high in monounsaturate** would provide significant health benefits to the United States population, as well as, economic benefit to oil processors. Soybean varieties which produce seeds containing the improved oil will also produce valuable meal as animal feed.” (Emphasis added).

Hitz et al. also states in column 2 at lines 48-56 that soybean oil with increased levels of stearic acid would be expected to produce a cocoa butter substitute in soybean.

Thus, Hitz et al. does not teach transgenic soybeans containing increased stearic acid being valuable as animal feed. Rather, such soybeans may have value in producing a cocoa butter substitute.

Zwick et al. teaches nucleic acid molecules encoding delta-9 desaturase gene, expression vectors, plant cells and transgenic plants expressing delta-9 desaturase. It is noted that page 6 of the Office Action references column 32 at lines 32-34 of Zwick as teaching grain. However, it teaches seed from transgenic corn plants produced for the **GBSS** target. GBSS is identified in column 12 of Zwick at lines 52-54 as **granule bound starch synthase**. Zwick does mention collection of R₁ seed from transgenic corn plants produced for the delta-9 target in column 33 at lines 4-5. However, these seeds do not appear to have been analyzed for the phenotype. It is not clear that this seed possesses the desired phenotype.

Based on the discussion in Examples 28-30, it appears that leaves were analyzed with respect to phenotype. Example 30, Part C concerned a demonstration of reduction of delta-9 desaturase levels in R0 **maize leaves** expressing ribozymes targeted to delta-9 desaturase mRNA.

Zwick et al. states in column 16 at lines 7-10 that "Applicant believes that reduction in oleic and linoleic acid levels by down-regulation of Δ -9 desaturase activity will make corn a viable alternative to soybean and canola in the saturated oil market." Zwick et al. does not appear to mention feeding an animal a corn grain from a transgenic plant as described in Zwick.

Furthermore, the instant claims now recite that chimeric gene comprises, among other things, an isolated nucleic acid sequence encoding a corn delta-9 desaturase **consisting essentially of** the amino acid sequence set forth in SEQ ID NO:9.

Accordingly, it is respectfully submitted that it would not have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Hitz et al. (which concerns soybeans) and Zwick et al. to produce a method for feeding an animal using transgenic corn grain taught by Zwick.

In addition, Zwick et al. have not demonstrated that the seed obtained from transgenic corns plants targeted to delta-9 desaturase RNA have the desired phenotype. Parenthetically, it is noted that Zwick only provides data for seed collected from plants produced for the **GBSS** target. No seed data is provided for seed collected from plants produced for the delta-9 target. It appears that Zwick could have provided such seed data but did not. Zwick does provide data for leaves collected from plants produced for the delta-9 target. Zwick et al. does not teach a method of feeding an animal.

Hitz et al. does teach the use of high stearate soybeans as a possible cocoa butter substitute. (Column 2 at lines 48-56) not as animal feed.

Thus, one skilled in the art would not have been motivated to provide a method for feeding an animal comprising feeding the animal the transgenic corn grain of the instant invention which recites, among other things, an isolated nucleic acid sequence encoding a corn delta-9 desaturase consisting essentially of the amino acid sequence set forth in SEQ ID NO:9.

In view of the foregoing discussion, withdrawal of the rejection of claims 172 and 176 under 35 USC §103(a) as being unpatentable over Hitz et al. (US 5443974) in view of Zwick et al. (US 6350934) is respectfully requested.

Claims 173 and 176 were rejected under 35 USC §103(a) as being unpatentable over Hitz et al. (US 5443974) in view of Lightner et al. (WO 94/11516) and Zwick et al. (US 6350934).

It is respectfully submitted that combined teachings of Hitz et al., Lightner et al. and Zwick et al. do render the claimed invention obvious. None of the references teach a method for feeding animals as set forth in the claims of the instant invention.

Hitz et al. and Zwick et al. are discussed above.

Zwick et al. discussed a transgenic corn targeted for delta-9 desaturase not high oleic. There is no demonstration that the seed obtained from such transgenic corn plant had the desired phenotype. Only leaf data was provided. The only seed data provided concerned corn targeted for GBSS.

Lightner, WO 94/11516, published May 26, 1994, describes genes for microsomal delta-12 desaturases and related enzymes from plants. The cloning of a corn (*Zea mays*) cDNA encoding seed microsomal delta-12 fatty acid desaturase is described.

One of ordinary skill in the art would not have been motivated to produce a method of feeding an animal comprising feeding an animal a corn grain obtained from a transgenic plant comprising in its genome a chimeric gene as is recited in the claims based on the teachings of Hitz et al. which concerned soybeans with Zwick et al. concerning transgenic corn targeted for GBSS or delta-9 desaturase (and no data showing seeds obtained from transgenic corn plants targeted for delta-9 desaturase as having the desired oil phenotype) and Lightner et al. which concerns the cloning of a corn cDNA encoding seed microsomal delta-12 fatty acid desaturase.

Hitz et al. does mention in column 2 at lines 22-27 that soybeans producing seeds having oil high in monounsaturate and low in total saturates and polyunsaturates might also produce valuable meal as animal feed. But, Zwick concerns transgenic corn plants targeted for delta-9 desaturase. The leaf data provided demonstrated an increase in stearic acid content. Lightner et al. concerns plants having an altered oleic acid content. Such transgenic corn plants were not exemplified by Lightner et al. Hitz et al. does not suggest that high oleic corn grain might be useful in a method of feeding an animal as is recited in the instant claims.

In view of the foregoing, withdrawal of the rejection of claims 173 and 176 under 35 USC §103(a) as being unpatentable over Hitz et al. (US 5443974) in view of Lightner et al. (WO 94/11516) and Zwick et al. (US 6350934) is respectfully requested.

Claim 174 was rejected under 35 USC §103(a) as being unpatentable over Hitz et al. (US 5443974) in view of Lightner et al. (WO 94/11516) and Zwick et al. (US 6350934) as applied to claims 173 and 176, and further in view of Kossman et al. (WO 95/07355).

With respect to SEQ ID NO:9, claim 174 now recites that the isolated nucleic acid fragment encodes a corn delta-9 stearoyl ACP desaturase consisting essentially of the amino acid sequence set forth in SEQ ID NO:9. Furthermore, the claims also recite that all or part of the isolated nucleic acid fragment is useful in co-suppressing an endogenous gene encoding a corn delta-9 stearoyl ACP desaturase.

Hitz et al., Lightner et al. and Zwick et al. are all discussed above.

Kossman et al. does not overcome the shortcomings of Hitz et al., Lightner et al. and Zwick et al.

Kossman et al. appears to be concerned with modifying starch in plants. Kossman does not teach a method for feeding an animal a corn grain obtained from a transgenic corn plant comprising in its genome any of the chimeric genes recited in the claims.

None of the references either alone or in combination teach the method of the instant invention for all of the reasons discussed above.

Accordingly, withdrawal of the rejection of claim 174 as being unpatentable under 35 USC §103(a) over Hitz et al. (US 5443974) in view of Lightner et al. (WO 94/11516) and Zwick et al. (US 6350934) as applied to claims 173 and 176, and further in view of Kossman et al. (WO 95/07355) is respectfully requested.

Claims 173, 175 and 176 were rejected under 35 USC §103(a) as being unpatentable over Hitz et al. in view of Lightner et al. and Zwick et al. as applied to claims 173 and 176 and further in view of Kriz et al. (US 6307123) and Vasil et al. (US 5955330).

Hitz et al., Lightner et al. and Zwick et al. are all discussed above.

Kriz et al. teach identification of transgenic seed by using screenable markers linked to aleurone-specific promoters.

Vasil et al. teaches enhancing expression of a structural gene using the first intron and exon of the maize shrunken 1 gene enhancer.

It is respectfully submitted that the disclosures of Kriz et al. and Vasil et al. do not overcome the deficiencies of the cited references in view of the above discussion. It would not have been prima facie obvious to have modified the constructs of Lightner et al. to have also included the corn oleosin L3 promoter taught by Kriz because Kriz et al. was concerned with identification of transgenic seed by using screenable markers linked to aleurone-specific promoters. It would not have been obvious to make a method of feeding an animal comprising feeding the animal a corn grain obtained from a transgenic corn plant comprising in its genome a chimeric gene as is recited in the claims based on the teachings of Hitz et al. in view of Zwick et al. and Lightner et al. for all of the reasons discussed above. The teachings of Vasil et al. do not overcome the deficiencies of the cited combination of references.

There is simply no teaching or suggestion to combine the teachings of Hitz et al. concerning soybeans with altered oil profiles (e.g., the use of high stearic soybeans to make a cocoa butter substitute) with Zwick et al. concerning transgenic corn targeted for altered starch and delta-9 desaturase but which provides no data concerning seed obtained from transgenic corn plants targeted to delta-9 desaturase and which does not mention a method for feeding animals with Lightner et al. which

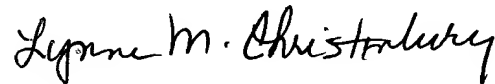
concerns transgenic plants and seeds obtained therefrom having an altered oleic acid phenotype with Kossman et al. or Kriz et. al. or Vasil et al.

Accordingly, withdrawal of the rejection of Claims 173, 175 and 176 were under 35 USC §103(a) as being unpatentable over Hitz et al. in view of Lightner et al. and Zwick et al. as applied to claims 173 and 176 and further in view of Kriz et al. (US 6307123) and Vasil et al. (US 5955330) is respectfully requested.

It is respectfully submitted that the claims are now in form for allowance which allowance is respectfully solicited.

Please charge any fees or credit any overpayment of fees which are required in connection with the filing of this Response and Petition for Extension of Time to Deposit Account No. 04-1928 (E. I. du Pont de Nemours and Company).

Respectfully submitted,



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